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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,799	07/14/2003	Robert M. Landis	991-8	5785
7590	07/26/2005		EXAMINER	
David M. Carter Carter, DeLuca, Farrell & Schmidt, LLP Suite 225 445 Broad Hollow Road Melville, NY 11747			ALI, SHUMAYA B	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 07/26/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Tattn

Office Action Summary	Application No.	Applicant(s)	
	10/618,799	LANDIS, ROBERT M.	
	Examiner Shumaya B. Ali	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7/14/03.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) 13 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>DETAILED ACTION</u> . |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, drawn to a continuous positive airway pressure (CPAP) system.
 - II. Claims 16-23, drawn to an interface used with CPAP
 - III. Claims 24-25, drawn to a method of treating with CPAP

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be sued to practice another and materially different process.
3. Restriction is required between groups II and I since group I is drawn to a CPAP system and group II is drawn to an interface used with a CPAP system.
4. During a telephone conversation with Frank Sardone on 7/19/2005 a provisional election was made with traverse to prosecute the invention of group I, claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-3,12-15, rejected under 35 U.S.C. 103(a) as being unpatentable over Keifer US 6,769,432 B1.**

7. **As to claim 1, Keifer discloses** a continuous positive airway pressure system comprising, an interface defining a plenum chamber (**fig.2 reference object 10**) therein, wherein the interface is connectable to a ventilation circuit for delivering pressurized air to the plenum chamber; and a pair of nasal cannula (**fig.2 reference object 22**) connected to and in fluid communication with the interface, the nasal cannula being configured and dimensioned to deliver pressurized air to the nares of a patient, wherein each nasal cannula is capable of at least one of off axis movement and off axis pivoting (**rubber construction, col.1 lines 37-38, of the cannula is considered flexible, and all flexible objects are capable of providing some degrees of movement**).

8. **As to claim 2, Keifer discloses** a portion of the interface is fabricated from elastic material ("rubber" is considered elastic, **col.1 lines 37-38**).

9. **As to claim 3, Keifer discloses** a conduit ("air delivery apparatus") internally disposed within the interface, wherein the conduit extends from the ventilation circuit to a location in close proximity to the nasal cannula (**col.2 lines 59-61**).

10. **As to claim 4, Keifer does not disclose** the conduit is flexible, however it is well known in the art that the gas delivery tubes/conduit used in the positive airway pressure system are inherently flexible so that the tubes can be easily curved or bent to pass through/over award surface.

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11. As to claim 12, Keifer discloses an annular trough (fig.2 seems to depict depth spaces around the nostril stems. The depth spaces are considered annular trough allowing movement while preventing the stems from collapsing or kinking).

12. As to claim 13, applicant discloses on page 13 line 2 of the disclosure that the cannula can be flared, fluted, or frustoconical. Since no criticalities regarding the shape of the cannula has been established, the shape is considered an obvious design choice. The cannula as disclosed by Keifer in figure 2 is considered flared.

13. As to claim 14, Keifer discloses the interface is fabricated from silicone (col.1 lines 37-38).

14. As to claim 15, Keifer discloses each nasal cannula is capable of at least one of off axis movement and off axis pivoting without kinking (fig.2 seems to depict depth spaces around the nostril stems. The depth spaces inherently capable of allowing movement while preventing the stems from collapsing or kinking).

Claim 5,6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keifer US 6,769,432 B1 in view of Landis et al. US Patent 5,687,715.

15. As to claims 5 and 6, Keifer does not disclose/teach overall claimed subject matters. As to claims 5 and 6, Landis et al. teach a nasal positive airway pressure apparatus with an elastic venting orifice that expands in response to increased gas pressure or under other increased pressure conditions to relieve excess pressure, and returns to its original reduced aperture size when venting is not required (col.4 lines 35-48). The unique expandable nature of the vent is considered capable of allowing high-exhaled air volume to pass through. Therefore, it would have been obvious to one in ordinary skills in the art to add the expandable vent to the

invention of Keifer for the purposes of allowing high exhaled air volume to pass through to further enhance breathing comfort.

16. **As to claim 8, Keifer discloses a support stem (fig 2 reference object 12)**

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keifer US 6,769,432 B1 in view of Landis et al. US Patent 5,687,715. and Lithgow US Patent 6,422,238 B1

17. **Keifer does not disclose specific limitations to the bonnet in claims 9-11. However, it is obvious that the device has some form of securing system to securely hold the device to the patient. As to claims 9-11, Lithgow teaches a headgear ("bonnet") for securing an interface ("mask") to a patient incorporates a quick release arrangement, straps, body portion with slits and hook and loop fasteners attached to the straps (see abstract and fig.3). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to add a bonnet in view of Lithgow for the purposes of securing the interface to the patient.**

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keifer US 6,769,432 B1 in view of Landis et al. US Patent 5,687,715. and Drew et al. US 6,823,865 B2.

18. **As to claim 7, Keifer does not disclose a vent cover. As to claim 7, Drew et al. teach a respiratory mask ("interface") with a gas washout vent assembly comprising an opening with a thin air permeable membrane extending across said opening ("cover") (col.3 lines 62-63). Therefore, it would have been obvious to further modify the vent of Keifer in view of Drew et al. to add an air permeable membrane for the purposes of allowing gas to quietly exit from the breathing cavity and capable of functioning as a vent cover.**

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Claim Objections

19. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

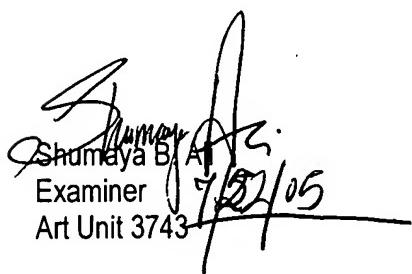
Misnumbered claim 13 been renumbered 14.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

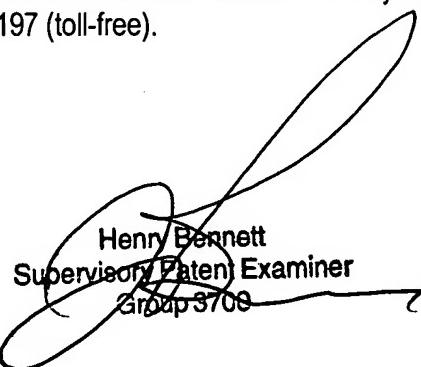
21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shumaya B. Ali
Examiner
Art Unit 3743

7/21/05



Henry Bennett
Supervisory Patent Examiner
Group 3700